UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,013	08/06/2003	Steven W. Collier	PC23199A	1525

23913 7590 09/06/2007

PFIZER INC
Steve T. Zelson
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
LAMM, MARINA	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,013	COLLIER ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9-11,16,17 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7, 9-11, 16, 17 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 6/28/07. Claims pending are 1, 7, 9-11, 16, 17 and 20-28. Claims 2-6, 8, 12-15, 18, 19 and 29-78 have been cancelled. Claims 1, 7, 9, 16, 20, 23 and 26 have been amended. The previously filed amendments dated 5/8/06 and 7/26/06 have not been entered because they were non-compliant with the requirements of 37 CFR 1.121. See Notices dated 7/19/06 and 5/29/07.

Double Patenting

1. All double patenting rejections set forth in the previous Office Action dated 2/6/06 are maintained for the reasons of the record. It is noted that the Applicant intends to address the ODP issues of record once the claims of the instant application are otherwise in condition for allowance. See p. 5 of the reply.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 7, 9, 10, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Curatolo et al. (EP 679 400), of record.

Curatolo et al. teach a powder for oral suspension containing azithromycin, flavorants (e.g. vanilla, banana, etc.) and wetting agents such as sorbitan monolaurate and polysorbate 80. See p. 7, lines 2-37. The powder of Curatolo et al. may also contain artificial sweeteners. See p. 7, lines 20-21. The azithromycin of Curatolo et al. includes

the pharmaceutically acceptable salts thereof, as well as *anhydrous* and hydrated forms. See p. 4, lines 39-40. The teaching of the "anhydrous" form of azithromycin anticipates the claimed limitation "non-dihydrated azithromycin". The flavorants of Curatolo et al. anticipate the claimed limitation "an azithromycin form conversion enhancer"; the wetting agents of Curatolo et al. anticipate the claimed limitation "an azithromycin form conversion stabilizing excipient".

Thus, Curatolo et al. teach each and every limitation of Claims 1, 7, 9, 10, 16 and 17.

4. Claims 1, 7, 9, 10, 16, 17, 20, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tenengauzer et al. (US 6,764,997), of record.

Tenengauzer et al. teach stabilized azithromycin dosage forms, including powders to make oral suspension, comprising flavorants such as vanilla, grape and banana ("an azithromycin form conversion enhancer" of the instant claims), wetting agents such as sorbitan monolaurate and polysorbate 80 ("an azithromycin form conversion stabilizing excipient" of the instant claims), and sweeteners. See col. 5, lines 9-24; col. 6, lines 32-60. Tenengauzer et al. teach azithromycin ethanolate monohydrate (form F) as the preferred azithromycin form. See col. 3, lines 1-6.

Thus, Tenengauzer et al. teach each and every limitation of Claims 1, 7, 9, 10, 16, 17, 20, 21, 23 and 24.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 20, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243), all of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed forms of azithromycin. However, Tenengauzer et al. teach using azithromycin ethanolate monohydrate (form F) in stabilized powders for oral suspensions as discussed above. Alternatively, Li et al. teach using the azithromycin forms of the instant claims in pharmaceutical compositions, including powders for oral suspensions. See col. 2-4; col. 26, lines 35-36. The crystal forms of azithromycin show improved stability as compared to form A. See col. 14, lines 40-50. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanolate monohydrate or other non-hydrate crystal forms of azithromycin instead of anhydrous azithromycin. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by either Tenengauzer et al. or Li et al.

The applied reference (Li et al.) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

7. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of either Tenengauzer et al. or Li et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima*

facie obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574), both of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed ethanol solvate form of azithromycin. However, Singer et al. teach using azithromycin ethanol solvate in pharmaceutical compositions because it is less hygroscopic than azithromycin monohydrate. See col. 1, lines 60-65; col. 3, line 26. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanol solvate. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Singer et al.

9. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of Singer et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners.

However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

10. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903), both of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed isopropanol solvate form of azithromycin. However, Karimian et al. teach using azithromycin isopropanol solvate in pharmaceutical compositions because it is a non-hygroscopic form of azithromycin and, therefore, is more stable than anhydrous azithromycin. See col. 2, lines 35-41; col. 3, lines 22-60. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin isopropanol solvate. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Karimian et al.

11. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of Karimian et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Artman et al. (US 6,383,527), both of record.

Curatolo et al. applied as above. Curatolo et al. teach various flavorants as discussed previously. The reference does not teach the compounds claimed in the instant claim. However, it is well known in the art of pharmaceutical and food compositions to use isoamyl isovalerate of the instant claim as an FDA-accepted flavoring agent. See Artman et al. @ col. 8, lines 6-12. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use isoamyl isovalerate

for its art-recognized purpose as a flavoring agent. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavor/aroma of the composition.

Response to Arguments

13. Applicant's arguments filed 6/28/07 have been fully considered but they are not persuasive.

In response to the Applicant's argument that "Curatolo does not disclose any powders for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application" (see p. 5 of the reply), it is noted that the flavorants of Curatolo et al. anticipate that limitation as discussed above. Further, the Applicant argues: "Curatolo does not disclose any formulation containing an azithromycin form conversion enhancer, let alone an oral suspension comprising a non-dihydrate azithromycin, a non-dihydrate azithromycin form conversion stabilizing excipient, and an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application." See p. 5 of the reply. In response, the following is noted: (1) the instant claims are directed to a powder rather than formulation or suspension; (2) the reference explicitly teaches all elements of the instant claims as discussed above; (3) for a reference to anticipate a claim, it is not necessary to exemplify the claimed composition – the reference's disclosure is not limited to examples or preferred embodiment and must be considered as a whole.

In response to the Applicant's argument that "Tenengauzer does not disclose any powders for oral suspension comprising an azithromycin form conversion enhancer, let alone an oral suspension comprising a non-dihydrate azithromycin, a non-dihydrate azithromycin form conversion stabilizing excipient, and an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application" (see pp. 5-6 of the reply), it is noted that the flavorants such as vanilla, grape and banana, of Tenengauzer et al. anticipate the "an azithromycin form conversion enhancer" limitation of the instant claims as discussed above. Further, as discussed above, (1) the instant claims are directed to a powder rather than formulation or suspension; (2) the reference explicitly teaches all elements of the instant claims as discussed above; (3) for a reference to anticipate a claim, it is not necessary to exemplify the claimed composition – the reference's disclosure is not limited to examples or preferred embodiment and must be considered as a whole.

With respect to the 103(a) rejections over Curatolo et al. in view of secondary reference(s), the Applicant repeats the same argument, i.e. the combination of references "does not teach or suggest any powder formulation comprising an azithromycin form conversion enhancer as recited in amended claim 1." In response, as discussed above, the Curatolo et al. reference teaches each and every limitation of the instant claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
8/30/07

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER